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10/829,059	04/20/2004	Qing-Hua Zhao	USP2321C-DRSH	6780
30265	7590	11/14/2007	EXAMINER	
RAYMOND Y. CHAN			WALLENHORST, MAUREEN	
108 N. YNEZ AVE., SUITE 128			ART UNIT	
MONTEREY PARK, CA 91754			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/829,059

Applicant(s)

ZHAO, QING-HUA

Examiner

Maureen M. Wallenhorst

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising" and "comprises". Correction is required. See MPEP § 608.01(b).
3. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On the last line of claim 1, the phrase "a first data of health condition" is indefinite and vague since it is not known what is meant by this phrase. Does this phrase refer to the health condition of a patient from whom the testing sample was obtained? No patient whose health condition is to be monitored using the medical test kit is positively recited. In addition, this phrase does not make proper grammatical sense. See these same problems with the phrase "a second data of health condition" on the last two lines of claim 2, and with the phrase "a third data of health condition" on the last line of claim 3.

Claim 4 is indefinite and improper since it depends from independent kit or apparatus claim 1, and claim 4 recites method steps. Claim 4 is indefinite since the method steps it recites do not further limit the physical elements of the kit recited in claim 1. On lines 1-2 of claim 4,

the phrase "a tangible information of method of dynamic recordation" does not make proper sense. It is not clear what physical element this amounts to in the kit of claim 1. The dynamic recordation diagram recited in claim 4 is indefinite since it is not clear whether this is a chart to simply record the results obtained from combining a test sample with each of the compositions in the first, second and third plurality of testing compositions, and comparing the results recorded with results present in the chart that are representative of a healthy condition, a doubt condition and an unhealthy condition.

Claim 5 is indefinite and improper since it depends from independent kit or apparatus claim 1, and claim 5 recites method steps. Claim 5 is indefinite since the method steps it recites do not further limit the physical elements of the kit recited in claim 1. On lines 1-2 of claim 5, the phrase "a tangible information of method of selecting testing compositions" does not make proper sense. It is not clear what physical element this amounts to in the kit of claim 1. Does the kit positively contain an interactive reference chart having a self assessment portion, a suggested test portion and a possible illness portion?

Claim 6 is indefinite since it does not further limit the physical elements of the kit recited in independent claim 1. Rather, claim 6 merely recites method limitations for how to use the kit. It is not proper for claims that depend from an apparatus/kit claim to recite method limitations. On line 14 of claim 6, the phrase "said bilirubin testing unit" lacks antecedent basis since claim 2 positively recites a bilirubin testing composition. In parts (d1) and (d2) of claim 6, the word "forth" is misspelled and should be changed to --fourth--.

Claim 7 is indefinite since it does not further limit the physical elements of the kit recited in independent claim 1. Rather, claim 7 merely recites method limitations for how to use the kit.

It is not proper for claims that depend from an apparatus/kit claim to recite method limitations.

On line 14 of claim 7, the phrase "said bilirubin testing unit" lacks antecedent basis since claim 2 positively recites a bilirubin testing composition. In parts (d1) and (d2) of claim 7, the word "forth" is misspelled and should be changed to --fourth--.

On lines 8-10 of claim 8, it is unclear what the phrase "a difference for bilinogen concentration higher than 1/20 and for bilinogen concentration lower than 1/20" means. On lines 11-13 of claim 8, it is not clear what the phrase "a normal condition, an over active condition and an inactive condition" is in reference to. What exactly is being limited by the phrase "a normal condition, an over active condition and an inactive condition"? In claim 8, the units of concentration for the different analytes being measured (i.e. calcium, nitrite, etc) are not recited. Are the recited percentage concentration levels supposed to be percentages by weight, by volume, etc.? See all of these same problems in claim 9.

On lines 16-19 of claim 9, the units of "8U, 64U and 128U" are unclear. What does "U" represent? In addition, it is not clear that each of the recited ranges between 8U and 128U represents a normal condition, an over active condition or an inactive condition. Also, it is not clear what element the condition refers to?

The last paragraph of claim 11 is indefinite since claim 11 is a method for preparing a kit, and it is not clear from the last paragraph whether the kit is prepared by providing the first plurality of interpretation spectra as a positive component of the kit in addition to the first plurality of testing compositions since the last paragraph of claim 11 is a "wherein" clause rather than a positive step of the method. See this same problem in claims 12 and 13.

Claim 14 is indefinite since it depends from independent claim 11 that recites a method for preparing a medical testing kit. Therefore, the steps of analyzing the results with a dynamic recordation diagram recited in claim 14 do not further limit the preparation steps recited in claim 11. On lines 1-2 of claim 14, the phrase "a step (k) of analysis the results" does not make proper sense. The dynamic recordation diagram recited in claim 14 is indefinite since it is not clear whether this is a chart to simply record the results obtained from combining a test sample with each of the compositions in the first, second and third plurality of testing compositions, and comparing the results recorded with results present in the chart that are representative of a healthy condition, a doubt condition and an unhealthy condition.

On line 1 of claim 15, the phrase "further comprising a step (l)" is indefinite since claim 15 depends from claim 13, and the last step in claim 13 is step (j). Thus, the next step recited in claim 15 should be labeled as step (k). Claim 15 is indefinite since it depends from independent claim 11 that recites a method for preparing a medical testing kit. Therefore, the steps of selecting the testing compositions in response to an interactive reference chart recited in claim 15 do not further limit the preparation steps recited in claim 11. Do the steps for preparing the kit positively include a step of providing an interactive reference chart having a self assessment portion, a suggested test portion and a possible illness portion as an element of the kit?

On lines 8-10 of claim 16, it is unclear what the phrase "a difference for bilinogen concentration higher than 1/20 and for bilinogen concentration lower than 1/20" means. On lines 11-13 of claim 16, it is not clear what the phrase "a normal condition, an over active condition and an inactive condition" is in reference to. What exactly is being limited by the phrase "a normal condition, an over active condition and an inactive condition"? In claim 16, the units of

concentration for the different analytes being measured (i.e. calcium, nitrite, etc) are not recited.

Are the recited percentage concentration levels supposed to be percentages by weight, by volume, etc.? See all of these same problems in claims 17, 18 and 19.

On lines 16-19 of claims 17, 18 and 19, the units of "8U, 64U and 128U" are unclear.

What does "U" represent? In addition, it is not clear that each of the recited ranges between 8U and 128U represents a normal condition, an over active condition or an inactive condition. Also, it is not clear what element the condition refers to?

4. Claims 1 and 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a medical test kit and a method for preparing that comprises 1) a first plurality of testing compositions including a glucose testing composition having the specific components recited therein, a protein testing composition having the specific components recited therein, a blood testing composition having the specific components recited therein, a calcium testing composition having the specific components recited therein, and a nitrite testing composition having the specific components recited therein, and 2) a first plurality of interpretation spectra with respect to the glucose, protein, blood, calcium and nitrite testing compositions, wherein each interpretation spectra provides an interpretation result for each of glucose, protein, blood, calcium and nitrite to compare to a test result obtained by combining a test sample from a patient with each composition in the first plurality of testing compositions in order to evaluate the health of the patient based upon the glucose, protein, blood, calcium and nitrite test results.

5. Claims 2-10 and 12-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above, and in addition, since none of the prior art of record teaches or fairly suggests a medical test kit and a method for preparing that comprises in addition to the elements listed above in paragraph #4, a second plurality of testing compositions including a bilirubin testing composition having the specific components recited therein, a bilinogen testing composition having the specific components recited therein, and an amylase testing composition having the specific components recited therein, a second plurality of interpretation spectra corresponding to each of bilirubin, bilinogen and amylase, a third plurality of testing compositions including a ketone testing composition having the specific components recited therein and a pH testing composition having the specific components recited therein, and a third plurality of interpretation spectra corresponding to each of ketone and pH.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Giraud who teaches of a lancet system including test strips for detection of many different types of analytes such as glucose, nitrites, bilirubin, etc.; Fischer et al who teach of a colorimetric test strip in a kit for detecting one of hemoglobin, glucose, protein, amylase, etc. in a biological fluid; Smith et al who teach of a method for detecting ketones in urine samples; Habenstein who teaches of a diagnostic agent to detect ketone bodies; Robertson et al who teach of a multiple analyte detecting device for detecting multiple analytes in a blood or urine sample; Lu et al who teach of a test device for simultaneously detecting multiple



analytes; Zwanziger et al who teach of a home test kit for self-testing for a disease; and Fritz (US Patents 5,260,219 and 5,137,692) who teaches of a urine self-test for detecting urea nitrogen and ketones therein.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1797

mmw

November 6, 2007

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